Clinical Trials Management Systems Workspace
Face-to-Face Meeting
Oregon Health & Science University

SESSION: Reporting/Sharing SIG Breakout

Session Information	**Date: May 30, 2007** **Time: 1:30 p.m. – 4:30 p.m. PDT** **Presenter/Lead: Christo Andonyadis (CTMS Lead) and Rachel Nosowsky (DSIC Lead)** **Facilitator: Julie Holtzople** **Scribe: Karen Ryan**
Executive Summary	An overview of Reporting/Sharing Special Interest Group (SIG) Activities was presented. This discussion included a high-level scope validation of cancer Adverse Event Reporting System (caAERS), RDX, Clinical Trials Database (CTDB), Clinical Trials Object Model (CTOM), Janus (Food and Drug Administration [FDA] Repository), and Clinical Data System (CDS)/Clinical Data Update System (CDUS). The group then completed the requirements gathering activity for data sharing of clinical trials data with existing/new destinations. As part of this process, the group reviewed "Privacy/Intellectual Capital Terms and Conditions Decision Tree." A productive discussion regarding the different levels of security followed. The group agreed to complete a mapping of data areas to sharing levels.
Discussion	• The need for a protocol abstraction system, with protocol data accessible and shared across systems, was raised. • It was suggested that at the Steering Committee meeting in August, someone should propose using an existing system as the protocol definition system. • Rather than considering data sharing needs system by system, it was decided to break down needs by "data areas." General data areas include Protocol Abstraction (the information that anyone reading the protocol document can learn), Protocol Administration (only aggregate, accrual information, sponsor information, funding terms), Patient Demographics, Baseline Characteristics, Treatment or Intervention, and Evaluations/Outcomes/Responses. Each data area may have data collected at the patient level and at the protocol (aggregate) level. • Role-based access is an understood requirement. • Discussions took place about the timing of the data sharing (e.g., is there ever a need to share patient data while the trial is actively accruing?).
Requirements	

Req. #	Name	Description

Issues

Issue ID	Description
1	There is a critical need for a protocol abstraction system. All systems depend on the fundamental protocol information (arms, stratification, treatment dose, expected Adverse Events (AE), accrual rates, etc.). Development of a centralized, authoritative database for the protocol data should be a priority. Those currently developing systems are working together, sharing specifications on their study model. The Steering Committee should provide guidance on the priority.

2	CTDB should allow for just one definition as the authoritative version of protocol data. The agreed goal is that a study should reside only once in the CTDB. The CTDB data may need to be cleaned out to ensure only one entry for a study.
3	The group encouraged the decision makers to take into consideration the Physician Data Query (PDQ) system.
4	It is necessary to find a way to address the academic credit issue in the culture (the principal investigator's frequent approach to "patent before they publish"). This limits the ability or interest in sharing information early.
5	A goal is to have subset of protocol abstraction information that should always fall in the "Green" category of Data Security and Intellectual Capital's (DSIC) Decision Tree for Privacy; this may be already achieved by *clinicaltrials.gov*.
6	An important aspect of the data sensitivity category is the *validation* of the data. Being able to assure that shared data has been cleaned would be valuable. A suggestion was made to define risk assessment (patient characteristic).

Action Items

Assigned To	Description	Due Date

Attendance

#	First Name	Last Name	Affiliation
1.	Bridget	Adams	OHSU
2.	Christo	Andonyadis	NCI CBIIT
3.	Rhoda	Arzoomanian	Univ of Wisconsin
4.	Steve	Barnard	Intel
5.	Greg	Bielawski	Patient Advocate
6.	John	Brandt	UNM CRTC
7.	Leslie	Derr	NCI CBIIT
8.	Sharon	Elcombe	Mayo Clinic
9.	Allison	Geer	Velos, Inc.
10.	Lakshmi	Grama	NCI / OCE
11.	Julie	Holtzople	Booz Allen Hamilton
12.	Brenda	Maeske	SAIC

13.	Jomol	Mathew	Dana – Farber
14.	Shannon	McLeevy	OHSU
15.	Randy	Millikan	MD Anderson
16.	Bob	Morrell	WFU
17.	Susan	Pannoni	City of Hope
18.	George	Redmond	NCI / CTEP
19.	Karen	Ryan	Booz Allen Hamilton
20.	Kathryn	Schuff	OHSU
21.	Ann	Setser	NCI / CTEP